

REMARKS

A. Matters Not Related To Claim Rejections or Specification Objection

a. Restriction Requirement

Applicants confirm their election of claims 1 – 10 and hereby cancel claims 11 – 14 reserving all rights to file divisional applications. Additionally, claims 2 – 5 and 9 and 10 are canceled by this amendment.

b. Statement of Related Cases

The present application is one of a number of applications with disclosures having, at least in part, common priority. So the Examiner may be fully informed, the enclosed Statement of Related Cases sets forth the entire family of applications and the current status of each application.

c. Information Disclosure Statement

Applicants note the Examiner has stricken certain references from PTO-1449's as not considered since not included with the submission. Applicants believe these were submitted in the parent application and properly listed without submission. Nevertheless a new information disclosure statement is submitted enclosing these references and listing additional references subsequently known to Applicants and for the disclosure in this application to conform to that in related applications.

Applicants note certain references on previously submitted Forms PTO-1449 were stricken by the Examiner as not submitted. Applicants believe these were properly before the Examiner as having been submitted in the parent Application. In previous telephone call with the Examiner, the undersigned was informed the Examiner would consider references from a parent case if the PTO-1449 clearly identified the parent application in which the reference was cited. Pursuant to that telephone call, a new PTO Form 1449 is submitted citing references cited in the early PTO-1449 but not considered by the Examiner. The enclosed PTO-1449 is amended to identify the parent application in which the reference was originally cited.

B. Objections to Specification

a. Cross-Reference to Related Applications

In response to paragraph 7 of the Office Action, the cross-reference to related applications is amended to update serial numbers.

b. Title

Without stating agreement or disagreement with the Examiner's remarks regarding the title (paragraph 8 of the Office Action) and to expedite prosecution, the title is amended to reflect the Examiner's suggested title.

C. Claims

a. Double Patenting Rejecting

Addressing the double patenting rejection raised by the Examiner in paragraph 40 of the Office Action, a terminal disclaimer is enclosed with reference to commonly assigned U.S. patent application Ser. Nos. 10/674,324; 10/756,176 and 11/192,750. This is filed without admission of double patenting and solely to expedite prosecution.

b. Rejections Based On Prior Art

i. Summary Of Amendments To Claim 1

Claim 1 is amended to recite a method for treating a gastrointestinal disorder with a neural conduction block applied to a vagus nerve with the block selected to block both afferent and efferent signals along the nerve at the site of the block. Support for the claim amendment is found in the specification beginning on page 22 at line 20 describing a block (as used in the present claims) as a vagotomy-like procedure that prevents nerve transmission across the block site. This blocks both afferent and efferent signals. The Specification, e.g., on p. 22, line 23, notes a neural conduction block is similar to a vagotomy (severing of a nerve). A block acts on both afferent and efferent signals (toward and away from the brain). (Specification, p. 22, line 28). Blocking as an independent therapy is described in the Specification beginning on page 24 at line 15 and is shown in Fig. 8.

ii. **None of the References Describe Blocking A Nerve To Treat A Gastro-intestinal Disorder**

All vagal treatments involve imparting a signal to a vagus nerve for the signal to pass along the nerve. They intend to introduce a signal to the nerve. In certain references, e.g., Cohen '105 and Gross '909, the stimulation is accompanied by a so-called "collision block" which attempts to create a signal timed to interfere with the stimulation in one direction only (either afferent or efferent).

Marchal '862 is not a vagal-directed treatment. In fact, it teaches away from any treatment on a vagus nerve.

Applicants are aware that in a related application (Ser. No. 10/752,944), the same Examiner as in the present application has cited U.S. Patent No. 5,514,175 to Kim ("Kim") in a final Office Action dated October 16, 2004. Kim is cited with this amendment. Kim does not suggest any treatment on a vagal branch or trunk innervating an alimentary tract organ.

U.S. Patent No. 5,540,730 (Terry '730)

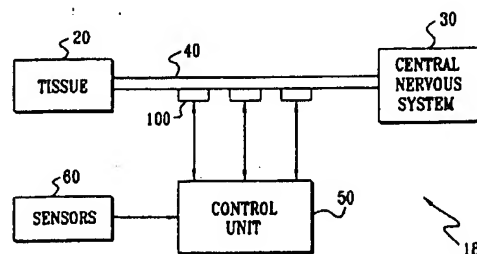
As noted by the Examiner, Terry '730 describes vagus nerve stimulation. Therefore, it teaches away from a treatment blocking both afferent and efferent signals.

U.S. Patent No. 6,684,105 (Cohen '105)

Cohen '105 is a stimulation treatment. Therefore, it teaches away from a treatment blocking both afferent and efferent signals.

Cohen '105 attempts so-called collision blocks. Cohen '105 is not suggesting treating anything with the block. Further, the collision block of Cohen '105 is not a neural conduction block as called for in the claims since it does not block both afferent and efferent signals.

Cohen '105 describes a purported technique for uni-direction nerve stimulation. Cohen '105 attempts to address adverse side effects were a neural impulse created by a stimulation therapy (such as the therapies of Terry '730) travels in both directions in a nerve. In one direction, the impulse travels to an intended organ for treatment. In an



opposite direction, the impulse can have unintended adverse effects.

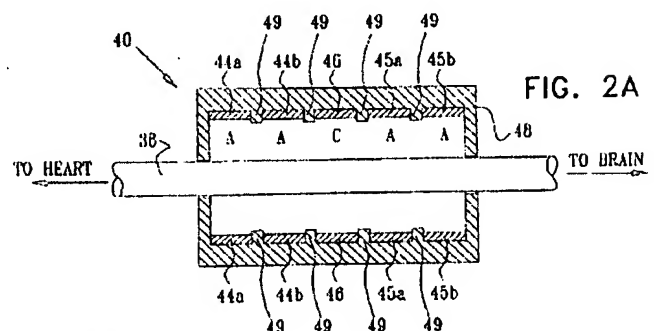
Cohen '105 attempts to restrict the travel in a desired direction by blocking neural impulses in an opposite direction. This is purportedly achieved by creating a second impulse in the nerve timed with the therapy impulse and positioned between a therapy electrode and an organ to be shielded from the therapy impulse. The two impulses collide preventing the wrong-directional therapy impulse from traveling to the shielded organ.

So-called "collision-blocks" as described by Cohen '105 have been criticized. For example, U.S. patent application Publication No. US2004/0093093 to Andrews published May 13, 2004, states, in paragraph 0012, "Collision block appears to have some potential drawbacks: The intense stimulus will excite anti-dromic pulses not only in--motor neurons in a mixed peripheral nerve. This will also excite other pathways (posterior horn and Renshaw cells) that may cause discomfort or unwanted reflex activity."

U.S. Patent Application Publication No. 2003/0045909 (Gross '909)

Gross '909 is commonly assigned with Cohen '105. Like Cohen '105 it is attempting to create so-called uni-directional stimulation. Therefore, it teaches away from a treatment blocking both afferent and efferent signals.

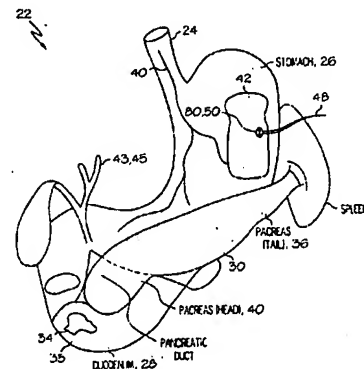
Like Cohen '105, Gross '909 attempts so-called collision blocks. Gross '909 is not suggesting treating anything with the block. Further, the collision block of Gross '909 is not a neural conduction block as called for in the claims since it does not block both afferent and efferent signals. In Gross '909, item 40 is an electrode intended to create a signal. (Gross '909, § 0194).



U.S. Patent No. 6,853,862 (Marchal '862)

Marchal '862 teaches away from a vagal-directed treatment.

"Vagal stimulation therapy is difficult to achieve and can adversely stimulate other organs. The electrodes used with vagal stimulation can also damage the vagus nerve by creating lesions." (Marchal '862, Col. 1, lines 48 – 51).




In view of the above amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Reconsideration and Notice of Allowance are solicited. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

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Timothy R. Conrad
Reg. No. 30,164

23552

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